K061204

# Section 5: 510(k) Summary

JUL 27 2006

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| **Submitted by:** | Masimo Corporation<br>40 Parker<br>Irvine, CA 92618<br>(714) 297-7000<br>FAX (714) 297-7001 |
| **Company Contact:** | James J. Cronin, Vice President, Regulatory Affairs |
| **Date Summary Prepared:** | May 1, 2005 |
| **Trade Name** | Masimo Rainbow SET® Radical 7 CO-Oximeter |
| **Common Name** | Pulse Oximeter and Sensor |
| **Classification Name** | Oximeter (74DQA)<br>Transducer and Electrode Cable (including connector) (74DSA)<br>Carbon monoxide test system (JKS)(862.3220) |
| **Substantially Equivalent Devices** | Masimo SET Rad-57cm and m Pulse CO-Oximeters<br>510(k) Number – K053477<br>Masimo SET Radical Pulse Oximeter with SatShare™ and Accessories<br>510(k) Number – K040214 |

**Description of Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter**

The Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter (Radical 7) with Rainbow technology is noninvasive monitoring of arterial oxygen saturation (%$SpO_2$), pulse rate, carboxyhemoglobin saturation (%SpCO), and/or methemoglobin saturation (%SpMet). The Radical 7 features an LCD display that continuously displays numeric values for %$SpO_2$ and pulse rate. Other information displayed by the Radical 7 include: %SpCO and/or %SpMet, Low Signal IQ (Low SIQ), Perfusion Index (PI), alarm status, alarm silence, battery life, sensor status, trends, and pleth waveform. The Radical 7 has output interfaces include: SatShare connection to multi-parameter monitors, Nurse Call analog output, and RS-232 serial output.

The Radical 7 is intended to be used with Masimo LNOP series of oximetery sensors, LNCS series of oximetery sensors, and patient cables. The Radical 7 is also intended to be used with Masimo Rainbow (SpCO/SpMet) sensors and Rainbow patient cables.

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Features and Benefits:

Clinically proven Masimo SET™ technology performance
Applicable for use on neonate, infant, pediatric and adult patients
Proven for accurate monitoring in no motion, motion, and low perfusion environments
Information display: $\%SpO_2$, pulse rate, %SpCO, and/or %SpMet, alarm, Perfusion Index, displays, Pleth waveform ($SpO_2$ measurement), Trends, Low Signal IQ (SIQ), battery life
FastSat™ (for $SpO_2$ measurement)
Three sensitivity levels - Max, Normal and APOD™ (for $SpO_2$ measurement)
Adjustable averaging 2 to 16 seconds
AC power or battery power (rechargeable batteries)
Alarm limits for $\%SpO_2$, pulse rate, %SpCO, and/or %SpMet
Audible Alarm for sensor-off and low battery
3D Alarm
Adjustable alarm volume
Trend memory of up to 30 days
SatShare interface with multi-parameter monitors
Nurse Call analog output
Serial output to printers, PCs, and chart recorders
Serial output to HP Vuelink
Serial output to Spacelabs Universal Flexport
Serial output to RadNet
Serial output to RadLink

**Intended use**

The Masimo SET® Radical 7 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin ($SpO_2$), pulse rate (measured by an $SpO_2$ sensor), carboxyhemoglobin saturation (measured by an SpCO/SpMet sensor), and/or methemoglobin saturation (measured by an SpCO/SpMet sensor) for adult, pediatric, and neonatal patients in hospitals, hospital-type facilities, mobile, and home environments.

**Indications for use**

The Masimo SET® Radical 7 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin ($SpO_2$), pulse rate (measured by an $SpO_2$ sensor), carboxyhemoglobin saturation (measured by an SpCO/SpMet sensor), and/or methemoglobin saturation (measured by an SpCO/SpMet sensor). The Masimo SET® Radical 7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. . In addition, the Masimo SET® Radical 7 Pulse CO-Oximeter and accessories is indicated to provide the continuous noninvasive monitoring data obtained from the Masimo SET® Radical 7 Pulse CO-Oximeter and accessories of functional oxygen of arterial hemoglobin ($SpO_2$) and pulse rate (measured by an $SpO_2$ sensor) to multi-parameter devices for the display of those devices.

**Principles of Operation**

*$SpO_2$ General Description*
Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults, and the hand or foot for neonates. The sensor connects to the pulse oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in two ways: 1) as a percent value for arterial oxygen saturation ($SpO_2$), and 2) as a pulse rate (PR).

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*SpCO And SpMet General Description*
Pulse CO-oximetry is a continuous and non-invasive method of measuring the levels of carbon monoxide concentration (SpCO) and oxidized hemoglobin concentration (SpMet) in arterial blood. It relies on the same principles of pulse oximetry to make its SpCO/SpMet measurements. The measurements are taken by placing a sensor on a patient, usually on the fingertip for adults. The sensor connects directly to the pulse CO-oximetry instrument or with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpCO and the SpMet. The Radical 7 is a combined $SpO_2$, SpCO, and/or SpMet monitor with the same setup as that of a pulse oximeter and can display $SpO_2$ in percentage values, pulse rate in beats per minute, SpCO in percentage values, and/or SpMet in percentage values.

Pulse oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), and methemoglobin (blood with oxidized hemoglobin content) species differ in their absorption of visible and infrared light.
2. The amount of arterial blood in tissue changes with your pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

The Radical 7 Pulse CO-Oximeter uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, and blood with oxidized hemoglobin content. Signal data is obtained by passing various visible and infrared lights (LED's, 400 to 1000nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. The photodetector receives the light, converts it into an electronic signal and sends it to the Radical 7 for calculation.

Once the Radical 7 receives the signal from the sensor, it utilizes Masimo SET signal extraction technology to calculate the patient's functional oxygen saturation, fractional concentrations of carboxyhemoglobin and methemoglobin, and pulse rate. The SpCO and the SpMet measurements rely on multiwavelength calibration equations to estimate the percentages of carboxyhemoglobin and methemoglobin in arterial blood.

**Method of Operation**

The Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter (Radical 7) is turned on. An oximetry sensor is attached to a patient's finger and one end of a patient cable is connected to the sensor and the other end connected to the Radical 7 Pulse CO-Oximeter.

The monitor will begin continuously displaying the patient's pulse rate, and $SpO_2$ value. If the Radical 7 is configured for SpCO and/or SpMet monitoring and the Rainbow sensor is attached to the patient's finger, then SpCO and/or SpMet values are also continuously displayed. The practitioner can then use the information that is continuously displayed on the monitor to help assess the condition of the patient and as an aide in determining if any intervention is required by the practitioner.

Once the practitioner determines the patient no longer requires monitoring, the cable is disconnected from the sensor, the CO-oximetry sensor is removed (and disposed of if it is a single use device), and the power to the monitor is turned off.

**Power Source**

The Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter is operated on AC power or battery power.

**Specifications and Operating Ranges**

| Range | |
|---|---|
| Oxygen Saturation (% $SpO_2$) | 1% - 100% |
| Carboxyhemoglobin Saturation (% SpCO) | 1- 99% |

| | |
|---|---|
| Methemoglobin Saturation (% SpMet) | 1- 99.9% |
| Pulse Rate (bpm) | 25 - 240 |
| Perfusion | 0.02% - 20% |

Accuracy

Oxygen Saturation (% $SpO_2$) - During No Motion Conditions

| | |
|---|---|
| Adults, Pediatrics[1] | 70% - 100% ± 2 digits |
| | 0% - 69% unspecified |
| Neonates[2] | 70% - 100% ± 3 digits |
| | 0% - 69% unspecified |

Oxygen Saturation (% $SpO_2$) - During Motion Conditions[3]

| | |
|---|---|
| Adults, Pediatrics | 70% - 100% ± 3 digits |
| | 0% - 69% unspecified |
| Neonates | 70% - 100% ± 3 digits |
| | 0% - 69% unspecified |

Oxygen Saturation (%$SpO_2$) - During Low Perfusion Conditions[4]

| | |
|---|---|
| Adults, Pediatrics | 70% - 100% ± 2 digits |
| Neonates | 70% - 100% ± 3 digits |

| | |
|---|---|
| Carboxyhemoglobin Saturation (% SpCO)[5] | 1% - 40% ± 3 digits |
| Methemoglobin Saturation (% SpMet)[5] | 1% - 15% ± 1 digits |

Pulse Rate (bpm) - During No Motion Conditions[1]

| | |
|---|---|
| Adults, Pediatric, Neonates | 25 to 240 ± 3 digits |

Pulse Rate (bpm) - During Motion Conditions[3]

| | |
|---|---|
| Adults, Pediatric, Neonates | 25 to 240 ± 5 digits |

Pulse Rate (bpm) - During Low Perfusion Conditions[4]

| | |
|---|---|
| Adults, Pediatric, Neonates | 25 to 240 ± 3 digits |

Resolution

| | |
|---|---|
| Oxygen Saturation (% $SpO_2$) | 1% |
| Carboxyhemoglobin Saturation (% SpCO), digital display | 1% |
| Methemoglobin Saturation (% SpMet), digital display | 0.1% |
| Pulse Rate (bpm) | 1 |

Interfering Substances

Carboxyhemoglobin and methemoblobin may erroneously increase oxygen saturation readings. The level of increase is approximately equal to the amount of carboxyhemoglobin and/or methemoglobin present. Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

Power

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|---|---|
| AC Power | 100 – 240 VAC, 47-63 Hz, 55VA |
| Rechargeable batteries | NiMH batteries |

Isolation

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|---|---|
| Chassis Leakage Current | Less than 100 µAmp |

| | |
|---|---|
| Ground resistance | Less than 1.0 Ω |

Environmental

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|---|---|
| Operating Temperature | 41°F to + 104°F (5°C to +40°C) |
| Storage Temperature | -40°F to + 158°F (-40°C to +70°C) |
| Relative Humidity | 5% to 95% noncondensing |
| Operating Altitude | 500 mbar to 1060 mbar pressure<br>-1,000 ft to 18,000 ft (-304 m to 5,486 m) |

Circuitry

Microprocessor controlled
Automatic self-test of oximeter when powered on
Automatic setting of parameters
Automatic alarm messages

Display

| | |
|---|---|
| Type | LCD |
| Data Displayed | SpO2 %, Pulse Rate, % SpCO and/or %SpMet, pleth waveform, alarm status, status messages, Signal IQ, perfusion index, sensor status, APOD, and FastSat |

Audio indicators

Adjustable volume audible pulse: OFF and 25% to 100% in 4 steps
Adjustable volume audible alarm tone: levels and 25% to 100% in 4 steps
Alarm silence (120 seconds); all mute (continuous silence)
Sensor condition alarms
System failure and battery low alarms

Physical characteristics

| | |
|---|---|
| Handheld Dimensions: | 8.9" x 3.3" x 2.1" (22.6cm x 8.4cm x 5.3cm) |
| Standalone Dimensions: | 3.5" x 10.5" x 7.7" (8.9cm x 26.7cm x 19.6cm) |
| Handheld Weight: | 1.3 lbs (0.32 kg) |
| Standalone Weight: | 5.4 lbs (2.45 kg) |

Modes

| | |
|---|---|
| Averaging mode: | 2, 4, 8, 10, 12, and 16 seconds |
| Sensitivity | Normal, APOD, and MAX |

1 The Masimo SET Technology with LNOP sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% $SpO_2$ against a laboratory CO-oximeter and ECG monitor.

2 The Masimo SET Technology with LNOP sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% $SpO_2$ against a laboratory CO-oximeter and ECG monitor. 1% has been added to the saturation accuracy to account for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

3 The Masimo SET Technology with LNOP sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% $SpO_2$ against a laboratory CO-oximeter and ECG monitor. 1% has been added to the saturation accuracy to account

for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

4 The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and a Masimo simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

5 The Masimo SET Rainbow Technology with Rainbow DC-dc sensors have been validated in human blood on healthy adult volunteers against a laboratory CO-oximeter from 1-40% for carboxyhemoglobin and 1-15% for methemoglobin. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

**Environmental Testing**

Applicable environmental testing per the Reviewers Guidance for Premarket Submissions - November 1993, i.e. electrical, mechanical and environmental were performed and all tests **passed**.

**Biocompatibility Testing**

All patient contact materials were tested as Surface Devices with skin contact for prolonged contact duration (>24 hr to 30 days) as defined ISO-10993-1: 1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests. All patient contacting material **passed**.

**Nonclinical tests performed that support a determination of substantial equivalence.**

The Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories was subjected to bench testing using a simulator that determined the performance accuracy of the instruments against the simulator under the range of oxygen saturation and pulse rates that the device specify.

The results of the bench testing showed that the Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories returned the same oxygen saturation accuracy values within ± 2 digits and pulse rate values within ± 3 digits, under no motion condition, when compared to the simulators used.

**Clinical tests performed that support a determination of substantial equivalence.**

Clinical studies were performed using the Masimo Rainbow SET® Radial 7 Pulse CO-Oximeter on healthy adult volunteer subjects during no motion and motion conditions who were subjected to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

The Masimo SET Rainbow Technology with Rainbow DC-dc sensors have been validated in human blood on healthy adult volunteers against a laboratory CO-oximeter from 1-40% for carboxyhemoglobin and 1-15% for methemoglobin. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

**Conclusions**

The results of the **environmental testing** demonstrate that the Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories **met** the requirements of Reviewers Guidance for Premarket Submissions - November 1993.

The results of the **biocompatibility testing** demonstrates the all patient contacting material **met** the requirements of ISO-10993-1: 1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests for Surface Devices with skin contact for prolonged contact duration (>24 hr to 30 days).

# Section 5: 510(k) Summary

The results of the **bench testing** demonstrate that the Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter **meets** their performance requirements.

The results of the **clinical testing** demonstrate that the Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories **meet** their performance requirements during no motion and motion conditions.

The **non-clinical and clinical testing** performed demonstrates that the Masimo Rainbow SET® Radical 7 Pulse CO-Oximeter and accessories are safe, effective, and performs as well as the predicate devices, the Masimo SET® Rad-57cm and m Pulse CO-Oximeters (K053477) and the Masimo SET® Radical Pulse Oximeter (K040214). Therefore, the Masimo SET® Radical 7 Pulse CO-Oximeter and accessories are substantially equivalent to the mentioned predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2006

Mr. James J. Cronin
Vice President, Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

Re: K061204
Trade/Device Name: Masimo SET® Radical 7 Pulse CO-Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, JKS and DPZ
Dated: May 1, 2006
Received: May 9, 2006

Dear Mr. Cronin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

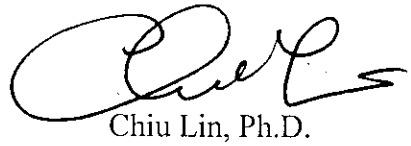
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Section 4 - Indications for Use

**510(k) Number (if known):**

**Device Name:** Masimo SET Radical 7 CO-Oximeter

**Indications For Use:**

The Masimo SET® Radical 7 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin ($SpO_2$), pulse rate (measured by an $SpO_2$ sensor), carboxyhemoglobin (measured by an SpCO/SpMet sensor), and/or methemoglobin saturation (measured by an SpCO/SpMet sensor). The Masimo SET® Radical 7 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition, the Masimo SET® Radical 7 Pulse CO-Oximeter and accessories is indicated to provide the continuous noninvasive monitoring data obtained from the Masimo SET® Radical 7 Pulse CO-Oximeter and accessories of functional oxygen saturation of arterial hemoglobin ($SpO_2$) and pulse rate (measured by an $SpO_2$ sensor) to multi-parameter devices for the display of those devices.

**Prescription Use** ___X_____ **AND/OR** **Over-The-Counter Use**

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

**(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

...n Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number K061204